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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,503

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Ryouichi Hoshino

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WASHINGTON, DC 20006-1021

EXAMINER

WESTERBERG, NISSA M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,503	Applicant(s) HOSHINO ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 - 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 - 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/23/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' arguments, filed June 23, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1 – 5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ohyama et al. (EP 1245232). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed January 22, 2008 and those set forth below. Due to the amendments to the claims, this rejection is applied to claims 3 – 5.

Applicant traverses this rejection on the basis that the trace amount of 4.8% of HPMC in Ohyama et al. is used as coating base for the tablets with active ingredients that are unstable to light. This amount of HPMC cannot function as a gel-forming material or sustained release base, the use of HPMC in the instant invention. The instant invention results in core with the active ingredient and an additive with less change in the formulation such as pregelatinized starch onto which the main ingredient is sprayed. Then HPMC and other additives are mixed in order to formulate tablets. A discussion of the process of making the product of Ohyama et al. and the instant invention is put forth. The product produced in Ohyama et al. immediately disintegrate upon contact with digestive juices and thus does not provide a sustained release function. In contrast, the HPMC of the instant invention can form a gel like material in the alimentary canal and provide a sustained release of the drug.

These arguments are not found to be persuasive. The Examiner was unable to find any mention of the use HPMC 2910 with the tradename TC-5, the viscosity of the preparation or the dissolution and/or drug release properties of the tablets in Ohyama et al. Citations by page/col and line number were not provided in Applicant's response and the document was searched for any mention of these terms, and none were found. The Examiner also cannot explain how different suppliers of HPMC 2910 at the same concentration and temperature results in solutions with viscosities of 3 – 15 cps and 4000 cps for the prior art and the instant invention respectively. As the 2910 part of the name refers to physical properties of the HPMC such as the hydroxypropyl and methyl content of the polymer, the basic HPMC material supplied should be chemically very similar so that an over 250-fold difference in the viscosity is very difficult to explain. If this data was obtained from experiments or other research by Applicant, Applicant is requested to submit that information in an appropriate form, such as a Rule 1.132 Oath/Declaration.

Applicant has submitted an IDS which references Alderman (US 4,734,285). This document discloses delayed release of an ingredient from a solid tablet using hydroxypropyl methycellulose ether (abstract). The use of a minimum amount of cellulose ether to provide the required delayed release is taught, with an exemplified range of from about 5% to about 90% by weight based on the total weight of the tablet (col 3, ln 3 – 13). This reference seems to contradict the statement made by Applicant that the 'trace' amount of HPMC used by Ohyama et al. is not capable of acting as a sustained release carrier. The viscosity of the HPMC 2910 viscosity and particle size is

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discussed, but “any size sufficient to form a gel-like layer can be employed” (col 2, ln 40 – 66). This would indicate that gels of HPMC can be formed using the amounts of HPMC cited by Alderman.

The newly added phrase “to manufacture a granular formulation for making tablets” is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The composition of the prior art could be used to make tablets and therefore it meets the claims.

While the products made in Ohyama et al. and instant claims are indicated by Applicant as being different, the preponderance of the evidence on the record at this time has not established that the product of the prior art is non-obvious over the instant claims, as required to render the product-by-process claims patentably distinct over the cited prior art. Therefore, this rejection is maintained.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 4 and 5 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/795,792. Due to the amendments to the claims, this rejection is WITHDRAWN.

7. Claims 3 – 5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/795,792 in view of Alderman (US 4,734,285). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application recite a sustained-release tablet comprising a gel-forming material and 4-2-(methyl-1-imidazolyl)-2,2-diphenylbutylamide. This compound is also known as imidafenacin (p 7, ln 16 – 18 of co-pending Application '792). As described in the co-pending application, a "multiple-unit oral sustained release preparation" uses granules or powders as the constituting unit (p 7, ln 23 – 25 and line 2 of claim 13). A tablet made by compacting the granules would therefore be a multiple-unit oral sustained release preparation. These tablets can be made compressing granulation, or a multiple-unit sustained release preparation of 4-2-(methyl-1-imidazolyl)-2,2-diphenylbutylamide as described in claim 13 of the copending application.

The claims of '792 do not recite the use of 18 – 73 weight% HPMC in the sustained release preparation.

Alderman discloses that HPMC such as that sold under the trade name METHOCEL® (see examples) can be used as the delayed releasing material in solid tablet formulations (abstract). The amount of this ingredient required to provide this function can be as wide as about 5 to about 90% or from about 10% to about 17% by weight based on the total weight of the tablet (col 3, ln 3 – 13).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a multiple-unit oral sustained release preparation of imidafenacin as recited in the claims of '792 and to prepare such a formulation using the amounts of HPMC taught by Alderman, arriving at the claims of the instant invention.

This is a provisional obviousness-type double patenting rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW